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THRESHOLD OF REGULATION POLICY – DECIDING WHETHER A PESTICIDE WITH A FOOD USE PATTERN NEEDS A TOLERANCE
October 18, 1999

I. EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA) is adopting a new policy regarding the use of pesticides on, in, or near food which do not result in residues that are detected in food. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), tolerances are needed for pesticide residues in or on food if such residues are not to render the food adulterated and subject to seizure. EPA regulations specify that all "needed" FFDCA tolerances associated with a pesticide use must be established prior to approval of that use under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Ordinarily, EPA considers that a specific use of a pesticide chemical needs a tolerance if the pesticide is used in a manner which has a reasonable likelihood to produce residues in food. In practice, EPA presumes that a pesticide used on, in, or near growing crops, livestock or food has a reasonable likelihood of resulting in residues in or on food.

EPA is adopting a policy that sets forth criteria for the Agency to consider in evaluating whether there is a need to establish a tolerance for a use of a pesticide where the use pattern of the pesticide would have previously been presumed to result in residues in food. Under the new policy, there would be no need for a tolerance or tolerance exemption under the FFDCA if: (a) using a reliable and appropriately sensitive analytical method to measure residues in the commodity, no residues are detected in the commodity under expected conditions of use when the commodity enters interstate commerce; and (b) using reasonably protective criteria, the estimated potential risk of any theoretically possible residues in food is not of concern. The Agency would regulate qualifying pesticide uses under FIFRA.

EPA generally will establish a regulation in 40 CFR for each pesticide use that meets the criteria established in this policy. In the event that EPA determines that a use no longer meets these criteria, EPA will revoke the regulation, and, if possible, establish a tolerance or exemption for residues resulting from the use.

EPA is adopting the Threshold of Regulation policy because it allows the Agency to approve registration of new pesticide uses or to permit the continuation of existing registrations of pesticide uses that pose "essentially zero" risk. The policy is intended to make Agency resources available for pre-market review of safer pesticides to replace pesticides that do not meet the new safety standard for tolerances established by the Food Quality Protection Act on 1996 (FQPA). It should also support a reasonable transition for agriculture by retaining some pesticide uses that might otherwise be discontinued and by expanding the number of potential replacements

for high risk food use pesticides.

II. BACKGROUND

A. EPA'S AUTHORITY TO REGULATE PESTICIDE RESIDUES IN FOOD

1. FIFRA

FIFRA authorizes EPA to register a pesticide if the proponent of registration presents data to show that use of the pesticide poses no unreasonable risk of adverse effects to humans or the environment and that its composition and labeling meet requirements under FIFRA section 3(c)(5) or 3(c)(7). FIFRA prohibits the sale or distribution of any unregistered pesticide unless the Agency authorizes an emergency exemption from FIFRA requirements under section 18 of FIFRA or issues a regulation exempting a pesticide from FIFRA requirements under section 25(b) of FIFRA. FIFRA also grants States the authority, subject to EPA review, to grant special local needs registrations under FIFRA section 24(c).

2. Coordination of Actions under FIFRA and the FFDCA.

While FIFRA governs the sale, distribution and use of a pesticide through a registration process and enforcement of the requirements on the pesticide label, the FFDCA provides a direct means of policing pesticide residue levels in food through tolerances or an exemption from tolerance for the pesticide residues. Under 40 CFR 152.112(g) and 152.113(a), EPA will not register the use of a pesticide if all needed tolerances or tolerance exemptions have not been established. If it is not possible to establish a needed tolerance or tolerance exemption for pesticide residues in or on food, EPA will not register the pesticide for the use which would result in such residues.

A pesticide that is used on, in, or near growing crops, livestock or food may require a tolerance or tolerance exemption, even if the pesticide is exempt from FIFRA requirements under FIFRA section 25(b).

3. FFDCA.

The FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that is "adulterated" (FFDCA section 301(a)). Food is deemed adulterated if, among other reasons, "it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a)" (FFDCA section 402(a)(2)(B)). Under FFDCA section 408(a)(1), "any pesticide residue in or on a food shall be deemed unsafe for the purposes of section 402(a)(2)(B) unless a tolerance . . . . is in effect . . . ." and residues are within the tolerance.

4. FQPA.

In 1996, the FQPA amended the FFDCA to clarify EPA's authority to establish a tolerance (or tolerance exemption) for residues of a pesticide active ingredient, any inert ingredient and any metabolites and degradates of active or inert pesticide ingredients that are in or on a food. The FQPA redefined "pesticide chemical" in the FFDCA to mean: "any substance that is a pesticide within the meaning of FIFRA, including all active and inert ingredients of such pesticide" (FFDCA section 201(q)(1)). The FQPA also added a definition of "pesticide chemical residue" (FFDCA section 201(q)(2)). This term means any residue of a pesticide chemical or any other substance that results primarily from the metabolism or degradation of a pesticide chemical. This definition makes explicit the long-standing EPA interpretation that the term "pesticide chemical" includes chemical compounds formed through the breakdown or metabolism of pesticidally active and inert ingredients of a pesticide formulation.

The FQPA significantly changed the basis for making a safety finding when establishing a tolerance. Under the new standard (FFDCA section 408(b)(2)(A) and (c)(2)(A)), the Agency must find that:

> There is reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

In addition to assessing exposure to pesticide residues in food and water, EPA must assess exposures, especially infants' and children's exposures, to pesticide residues in the home, garden, school, and outdoor play areas as well as any other non-occupational source.

Additionally, the Agency is required to assess the risk of a pesticide to infants and children considering: (a) available information on food consumption patterns among infants and children; (b) susceptibility of infants and children to the effects of pesticides, including neurological effects, from pre- or post-natal exposures to pesticide chemical residues; and (c) cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity in order to ensure that there is "a reasonable certainty of no harm" to infants and children. The statute further provides that an additional 10-fold margin of safety shall be applied for infants and children to take into account potential pre- and post-natal exposures and completeness of the data with respect to exposure and toxicity for infants and children unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children.

The FQPA amended FIFRA by adding section 2(bb)(2) to the FIFRA definition of "unreasonable adverse effects on the environment." The definition of "unreasonable adverse effects on the environment" now includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act . . . ." This addition was intended to improve coordination of the regulatory processes of FIFRA and FFDCA, as they affect pesticides.

5. FFDCA Sections 408 and 701.

FFDCA section 408(e)(1)(C) authorizes the Agency to establish general procedures and requirements to implement FFDCA section 408. FFDCA section 701(a) authorizes the Agency to establish rules implementing the various provisions of FFDCA, as follows: "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary." EPA understands the term "Secretary" to mean "Administrator" with respect to those provisions of FFDCA for which the Administrator of EPA, rather than the Secretary of Health and Human Services, has responsibility. These provisions grant EPA the authority both to promulgate a regulation to set criteria for Threshold of Regulation decisions and to identify by regulation pesticide uses that do not need tolerances or exemptions from tolerances under section 408 of FFDCA because they met such criteria.

B. CURRENT POLICY AND PRACTICE

1. Expansion of "Food Uses" of Pesticides.

Historically, EPA has always considered the application of a pesticide directly on a growing crop or on a raw agricultural commodity to be a use that is reasonably expected to result in pesticide residues in or on food. In more recent decades, the scientific community developed methods capable of detecting and analyzing smaller amounts of pesticide chemical residues in food and knowledge of the environmental fate and transport of pesticides increased. These developments led the Agency to expand the categories of pesticide use patterns that the Agency considers to be likely to result in residues in or on food and to begin requiring residue chemistry data to support such uses.

These potential "food uses" now encompass the use of a pesticide in virtually any aspect of food production, with certain exceptions as discussed below. For example, pesticides may be found in meat, milk, poultry or eggs derived from animals that were treated with pesticides or given feed containing pesticide residues. Water used to irrigate pesticide-treated fields may carry pesticide residues into other fields where the crops may accumulate residues. Pesticide applications to water that may subsequently contact food crops are also considered to be food uses. Moreover, because pesticides may persist in the soil and their residues may be found in subsequent crops, EPA may require residue chemistry data on "rotational crops" and on crops grown in soil that was treated with pesticides before planting.

Pesticides used in areas where food is stored, processed or handled may find their way into food. Antimicrobial pesticides may be used to sanitize food contact surfaces or to disinfect water in facilities where raw fruits and vegetables are packed[1]. EPA generally believes tolerances or tolerance exemptions are needed for all these uses.

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[1] The Antimicrobial Regulation Technical Corrections Act of 1998 (Public Law 105-324) clarifies FFDCA coverage of substances with antimicrobial activity that are used in, on, or around food.

2. Classification of Certain Agricultural Uses as “Non-food” Uses.

EPA found that residue chemistry and environmental fate data for some agricultural uses consistently showed that particular pesticide use patterns should be classified as “non-food” uses. The agricultural “non-food” uses of pesticides include soil treatment that occurs 12 months before planting of a food crop and treatment of a non-bearing fruit or nut tree 12 months before the tree begins bearing fruit. EPA does not require residue data to demonstrate that there are no residues in food as a result of such uses and does not require as extensive toxicology data set as is ordinarily required to support a food use.

3. Food Use Patterns

FFDCA section 402(a)(2)(B) stipulates that a food is adulterated “if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a).” In analyzing whether a pesticide use results in food which “bears or contains a pesticide chemical residue,” EPA can identify at least six different regulatory scenarios under this standard. These categories are not all mutually exclusive; rather some may be subsets of others.

The first category would include pesticide uses that do not result in even the theoretical presence of residues in food. For example, the pesticide may be applied in a sealed container in areas far removed from any food commodities.

Second, a pesticide might be presumed to theoretically result in residues in food because of application in the vicinity of growing crops but actual data reveal that no residues are present. Examples of uses in this category are described as “non-food uses” in unit II.B.2 above.

Third, the pesticide might be used in a manner that theoretically could result in residues, but data do not confirm that residues will be present and provide no basis for assuming that there will be any finite amount of residues present. Pursuant to 40 CFR 180.6, EPA makes such a determination (i.e., whether there is a reasonable expectation of finite residues) for milk, meat, poultry or eggs derived from animals directly treated with pesticides or fed pesticide-treated feed. If residues in animal products are below the LOQ of the method when livestock are treated with pesticides at 10 times the maximum rate or receive 10 times the expected exposure from treated feeds, or if animal metabolism studies show no likelihood of secondary residues in meat, milk, poultry and eggs, EPA’s practice has been to conclude that there is “no reasonable expectation of finite residues” in meat, milk, poultry and eggs (40 CFR 180.6(a)(3)) and to require tolerances only for the feed items, not for the animal products themselves.

Recently, EPA expanded this category when it concluded that there is “no reasonable expectation of finite residues” resulting from the use of fludioxinil as a seed treatment on corn and sorghum. The decision on the fludoxinil uses was characterized as a “food use without a tolerance.” The pesticide is unclassifiable as a human carcinogen, i.e., it is a Group D carcinogen; there was no “reference dose (RfD) exceedance” issue; there were sufficient hazard data to show

that infants and children are no more sensitive to the effects of the pesticide than the general population; and there were no acute toxicity endpoints of concern. No residues were detected in corn and sorghum derived from seed treated at 4X the proposed label rate. However, the Agency did not classify the use of fludoxinil seed treatment on potatoes as a "food use without a tolerance" because the data showed quantifiable residues in potatoes when the potato seed was treated at the 2X the proposed label rate.

Fourth, the pesticide might be used in a manner that does not result in detectable residues, but the available data suggest the potential for residues to be present in food. For example, studies using exaggerated application rates may find detectable levels of residue of the pesticide in the food. When pesticide residues in or on a food are so low that they cannot be detected, the Agency generally establishes a tolerance at the limit of quantification (LOQ). The LOQ is the lowest level of a pesticide residue that can be reliably measured in a particular commodity using a particular analytical method. Because the analytical method is not quantitatively reliable below the LOQ, measurements of residue levels between the limit of detection (LOD) and the LOQ can be used to demonstrate the presence of residues, but not their level. The LOD for a particular pesticide in a commodity as determined by a particular method often varies within and among laboratories. The variability of LOD measurements has led EPA not to use the LOD as the legal limit for pesticide residues in a food.

Fifth, a pesticide use may result in detectable residues. Sixth, even though a pesticide use may result in detectable residues those residue levels may be so low that the residue poses an insignificant risk.

This present policy statement addresses uses in the fourth, and in some cases, the third category, and concludes that certain of these uses do not "need" tolerances.

C. WHY A NEW POLICY IS BEING ADOPTED NOW

The FFDCA, as amended by FQPA, requires EPA to make a finding that aggregate, non-occupational exposures to pesticide chemical residues are reasonably certain to cause no harm. Under this provision, a tolerance may not be established for residues of any pesticide on any food unless the Agency finds that all dietary and other non-occupational exposures meet the safety standard. In the absence of a Threshold of Regulation Policy, a use that results in no detected residues in the food and that poses, at most, an extremely small risk may not be approved if risks of aggregate exposure to the pesticide, i.e., from existing uses, appear not to meet the safety standard.

The FFDCA, as amended by the FQPA, also requires EPA to establish time-limited tolerances under the FFDCA for residues in or on food resulting from a FIFRA Section 18 use of a pesticide. This change compelled EPA to depart from its former practice of evaluating the incremental dietary risk posed by the Section 18 use before authorizing the Section 18 exemption. In a few cases, EPA found that it could not establish tolerances under the FFDCA because the

existing aggregate exposure did not appear to meet the new FFDCA safety standard. Consequently, EPA did not grant the FIFRA Section 18 requests for emergency exemptions.

The regulated community, particularly growers who use pesticides on minor crops, has argued that EPA's application of the new FQPA safety standard has created a number of difficulties. Specifically, they assert that the more stringent regulation of residues resulting from FIFRA section 18 uses has resulted in denial or withdrawal of emergency exemption requests. As a consequence, growers claim they were unable in some cases to use pesticides that they needed to protect their crops. Growers believe that they were denied low-risk pesticide uses because of circumstances beyond their control.

III. A POLICY FOR DETERMINING WHEN A TOLERANCE IS NOT NEEDED

EPA is adopting a threshold of regulation policy for pesticide uses that result in no detected residues in food and for which the degree of potential **risk** posed by any theoretically possible residues is so minimal that tolerance setting serves no purpose. This policy will guide decision-making when risks from potential residues are too small to warrant FFDCA regulation.

Under this policy, the Agency would consider whether a tolerance is necessary for a pesticide use taking into account: (a) whether there are no detected residues using a reliable and appropriately sensitive analytical method to measure residues of the pesticide in any commodity that might have residues from such use, and, (b) whether, using reasonably protective criteria, the estimated potential risk from any theoretically possible residues in food resulting from such use is "essentially zero."

> *"No detected residues"* means that no residues are detected in or on any food commodity when the commodity enters interstate commerce[2]. The analytical method should have an LOQ no greater than 0.01 part per million (ppm) in any food commodity that might have residues from such use. EPA believes that this sensitivity can be achieved with most available methods.
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> *"Reasonably protective criteria"* means that incremental risk from exposure to potential residues in food resulting from use of a pesticide should generally be less than 1/1000 of the acceptable risk. The incremental potential risk from the use of a potentially carcinogenic pesticide should be below 1×10^{-9}. For a pesticide that exerts "threshold" effects, "reasonably protective criteria" means that the

[2]A raw agricultural commodity becomes subject to the FFDCA when it enters interstate commerce. EPA generally considers the "farm gate" to be the entrance to interstate commerce for such commodities. Therefore, processed foods or foods in commercial food storage, transport or preparation areas are already in interstate commerce. Accordingly, use of a pesticide in, on, or near a food after it has left the farm gate must not result in any detected residues in order for the use to be considered under this policy.

incremental acute or chronic potential exposure from the use occupies less than 0.1% of the acute or chronic population-adjusted dose[3] for the pesticide. EPA will consider potential risks to the most sensitive population, including an appropriate additional safety factor for infants and children, as required by the FQPA.

When estimating the potential risk from dietary exposures to any residues that may theoretically be present, EPA will generally use a level corresponding to ½ the LOD for the analytical method in the risk assessment. The reasons for selecting a value of ½ the LOD are discussed in a science policy paper entitled "Assigning Values to Nondetected/Nonquantified Pesticide Residues in Human Health Dietary Exposure Assessments.[4]" Alternatively, EPA may use another value as the level of any theoretical residues in the food if additional data on the fate of the pesticide, such as the data described below in unit IV.B.4, show that it is appropriate to use a value other than ½ LOD in the risk assessment.

IV. HOW EPA WILL APPLY THE POLICY

A. USES THAT ARE COVERED

This policy covers pesticides applied to or near growing crops or livestock as well as to pesticides used directly on or near food, such as insecticides or rodenticides used in areas where food is stored, transported, prepared or served and antimicrobial pesticides used in, on or around food. This policy is also applicable to inert ingredients because the definitions of "pesticide chemical" and "pesticide chemical residue" in the FFDCA include inert ingredients.

The Threshold of Regulation policy does not affect the procedures or the evaluation criteria given in 40 CFR 180.6 for determining whether it is necessary to establish a tolerance for pesticide residues in milk, meat, poultry or eggs derived from animals directly treated with pesticide or fed pesticide-treated feed. Under these procedures, the Agency will continue to rely upon metabolism and feeding studies as discussed in the EPA Pesticide Assessment Guidelines (Subdivision O, Residue Chemistry) to determine whether tolerances are needed for residues in milk, meat, poultry or eggs.

This policy does not apply to pesticide uses that EPA deems to be "nonfood" uses, i.e., uses that are not on, in or near growing crops, livestock or food. The policy also does not cover

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[3] The population-adjusted dose is the reference dose (RfD) adjusted by the FQPA safety factor for infants and children, if applicable.

[4] The availability of a draft version of this paper was announced in the Federal Register of December 4, 1998 (63 FR 76063). The OPP docket number for this paper is OPP-00570; an electronic copy may be viewed on EPA's website at http://www.epa.gov/fedrgstr/EPA-PEST/1998/December/Day-04/o-p32344.htm. EPA expects to release a revised version of this paper in March 2000.

measurable levels of "unavoidable" pesticide residues in or on foods, such as those resulting from uncontrollable or unavoidable presence of pesticide residues in air, water or soil. Because the policy covers situations where the residues have not been and are not expected to be detected, it does not apply to situations where measurable residues occur in food through environmental contamination.

B. ELIGIBILITY

A proponent of a proposed Threshold of Regulation use should demonstrate through the generation of appropriate data that the pesticide use does not result in residues detected in food and any potential residues pose "essentially zero" risk because the use meets the following criteria:

1. *Reliable residue data developed using an analytical method with appropriate sensitivity show that no pesticide residues are detected in the commodity, when the commodity enters interstate commerce, that result from the specific use of the pesticide.*

The gathering, processing, storage and analysis for residue levels in commodity samples should be conducted in accordance with EPA guidelines (EPA Pesticide Assessment Guidelines, OPPTS series 860, Residue Chemistry). The analytical method should have a LOQ no greater than 0.01 ppm (10 parts per billion) for residues in the commodity under consideration and should be an acceptable enforcement method. EPA thinks that this LOQ can be achieved in food matrices with most available methods. On a case-specific basis, EPA may require a lower LOQ or, if an appropriate rationale supports such a decision, accept a higher LOQ. To be acceptable as an enforcement method, the analytical method should be validated by an independent laboratory that is unfamiliar with the procedure.

Petitioners must explain clearly how the limits of detection (LOD) and quantitation (LOQ) were determined and should cite data or literature references describing such procedures. The Agency will closely examine raw data and chromatograms from crop field trials reflecting the proposed use to determine whether residues in the raw agricultural commodity(ies) (RAC) are below the LOD of the enforcement method. EPA may also need to determine whether detectable residues could occur in processed commodities derived from the treated RAC. Therefore, a processing study as outlined in OPPTS Guideline 860.1520 may be required, especially for crops such as citrus and mint which have very high theoretical concentration factors for their oils. The Agency may also assess whether detectable residues could occur in rotational crops grown after harvest of the treated crop. Thus, residues will need to be shown to be below the LOD in the treated RAC(s), processed commodities derived therefrom, and rotational crops planted later in the same field.

The Agency will consider surrogate data in the case of emergency exemption requests made under section 18 of FIFRA or minor use registrations where all the data needed on the

performance of the **analytical method** on the subject commodity may not be available. Given the emergency circumstances, EPA may consider accepting data on the performance of the analytical method on a different commodity.

The Agency will also consider surrogate data to support emergency exemption requests made under FIFRA section 18 where **field trial data** on the subject commodity are unavailable. As is presently done for establishing tolerances to support minor uses, the Agency may accept residue data from a related crop to establish eligibility for the threshold of regulation. EPA may also adopt the crop grouping concept from 40 CFR 180.41 when making Threshold of Regulation decisions. In other words, if residues are shown not to be detectable for the representative commodities of a crop grouping, it will be assumed residues are below the LOD in all other members of that crop grouping, provided that conditions of use are the same.

2. *There are sufficient data to characterize the hazard posed by any potential exposures to the pesticide.*

The toxicology data base for the pesticide typically should contain the data ordinarily required for pesticides with food uses. The toxicity data base should contain sufficient information to enable EPA to identify appropriate hazard end-points, identify a "no observed adverse effect level" (NOAEL) for each hazard end-point, and determine whether infants and children are likely to be more sensitive than the general population. As with all pesticides, including inert ingredients, the Agency will consider requests to waive data requirements on a case by case basis.

3. *Risk estimates show that any pesticide residues theoretically present in the food as a result of the use pose an "essentially zero" dietary risk.*

To be eligible for consideration under this policy, the dietary risk posed by residues that theoretically could be present in commodities as a result of the proposed use should be so low that it is not of regulatory concern. For purposes of this policy, EPA considers a risk that is less than 1/1000th of the acceptable risk for the general population and subpopulations to be a level of risk that is not of regulatory concern. In considering risk to subpopulations such as infants or children, EPA will use an additional safety factor where appropriate.

In estimating the risk from potential exposure to pesticide residues that may theoretically occur in food from a particular use, EPA will generally use a value corresponding to ½ the LOD of the analytical method as the level of pesticide residue in the food. A proponent of registration may present data to demonstrate that residues are not present at ½ the LOD and, if they are present in the food at all, that the residues would occur at some other level that is substantially lower than ½ the LOD. If reliable data show that a value substantially below ½ the LOD should be used as the level of any pesticide residues theoretically present in the food, EPA may use that level in its risk assessment.

If the exposure estimate presents a risk which is greater than 1/1000th of the acceptable risk, the use generally will not be considered under the Threshold of Regulation policy. In such cases, EPA generally will find that a tolerance or tolerance exemption in accordance with FFDCA section 408 is needed and the Agency would not approve use of the product under FIFRA without the tolerance or tolerance exemption needed under FFDCA.

4. *Supplemental information may be presented to demonstrate the absence of pesticide residues when the commodity enters interstate commerce.*

The Agency will examine information such as plant metabolism, environmental fate, and crop field trial data to determine whether a value other than ½ LOD of the analytical method should be used in assessing potential exposure from pesticide residues that may theoretically be present in the food.

Radio-labeled plant metabolism studies are useful in that they often involve a lower LOD/LOQ than the methods used to measure residues in field trials, i.e., the LOQ of such methods is below 0.01 ppm. Radio-labeled metabolism studies may also show that the plant degrades the pesticide into molecules that the plant uses in its natural growth cycle (i.e., bio-incorporation). Bio-incorporated residues are not pesticidally active and are generally not of regulatory concern.

The Agency will examine raw data and chromatograms from crop field trials to determine whether detectable residues are reasonably expected in the food. Studies conducted at pesticide application rates higher than those permitted on product labels are also often useful for this purpose. In addition, EPA may use residue decline data generated at application rates or pre-harvest intervals different from those proposed for the labeled use.

For estimating potential dietary exposure resulting from uses of antimicrobial pesticides on, in, or near food such as the use of antimicrobial pesticides on food contact surfaces, EPA may use models developed by the FDA. These include “Recommendations for Chemistry Data for Indirect Food Additive Petitions,” and “Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions.”

C. PROCEDURE

1. Assess Eligibility for Threshold of Regulation Status.

EPA will review data supporting a proposed or existing use to see if the use meets the criteria established in this policy. If the use qualifies as a Threshold of Regulation use, no tolerance will be established.

a. Applying the policy to prospective pesticide uses.

EPA generally will: a) make a Threshold of Regulation determination as part of the evaluation of any petition requesting a tolerance or exemption from tolerance (including those associated with FIFRA section 18 emergency exemption requests); and b) accept petitions for Threshold of Regulation decisions. Any interested party may apply for either a tolerance or tolerance exemption or a Threshold of Regulation decision for a new pesticide use. Persons wishing a Threshold of Regulation decision should make the request in writing and submit data that are ordinarily required to support a tolerance or a tolerance exemption, including data on processed food where applicable, to support the Threshold of Regulation petition. EPA reserves the right to collect a fee for evaluating Threshold of Regulation petitions, but will not charge a fee at this time.

b. Applying the policy to existing uses of pesticides.

EPA will determine, as part of the tolerance reassessment mandated by the FQPA amendments to FFDCA, whether pesticide uses covered by existing tolerances qualify for treatment under this policy. Because of workload considerations, EPA will assign a low priority to petitions to evaluate existing pesticide uses for conformance with the Threshold of Regulation Policy. Reviewing petitions to revoke tolerances for any existing pesticide uses that may qualify under the Threshold of Regulation Policy would be inconsistent with EPA's priority of devoting its tolerance reassessment resources, as far as possible, to the review of tolerances associated with the highest dietary risks.

2. FIFRA Review.

a. Proposed uses.

After deciding that no tolerance is required for a use, EPA would determine whether a proposed use meets the standard of registration in FIFRA section 3(c)(5), which requires – among other things – that the pesticide does not pose any unreasonable adverse effects, or section 3(c)(7)(B), which authorizes conditional registration of a use. FIFRA defines "unreasonable adverse effects" at section 2(bb), as follows: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug and Cosmetic Act . . . ." The FQPA amended FIFRA section 2(bb) by adding subparagraph (2) to improve regulatory linkage between FIFRA and the FFDCA. EPA believes that FIFRA section 2(bb)(2) does not apply to a registration decision when a tolerance is not required because use of the pesticide does not result in residues in or on the food. If a use meets the criteria set forth in the Threshold of Regulation Policy and the Agency determines that it is not necessary to establish a tolerance or tolerance exemption for any theoretical residues in food resulting from that use, the Agency has concluded that FIFRA 2(bb)(2) does not apply.

In accordance with FIFRA section 2(bb)(1), EPA will evaluate a proposed Threshold of

Regulation use to see whether it poses unacceptable risks to workers or wildlife under FIFRA 2(bb)(1). The Agency will also apply FIFRA section 2(bb)(1) to decide whether pesticide residues in drinking water that are attributable to the proposed use pose an unreasonable risk.

b. Existing uses.

As stated above in unit IV.C.1.b., EPA will determine, as part of tolerance reassessment, whether existing tolerances for a particular pesticide qualify for treatment under this policy. Because uses associated with tolerances or tolerance exemptions are already registered, EPA would not need to determine whether any existing uses that qualify as Threshold of Regulation uses meet the FIFRA standard for registration before implementing the Threshold of Regulation decision. EPA has two opportunities to assess whether an existing use that qualifies as a Threshold of Regulation use continues to meet the standards for registration established under FIFRA: 1) reregistration under section 4 of FIFRA; and 2) registration review under FIFRA section 3(g). When conducting a reregistration or registration review of a Threshold of Regulation use, EPA would apply the standard described above in unit IV.C.2.a.

D. IMPLEMENTING A THRESHOLD OF REGULATION DECISION

1. Publish a Threshold of Regulation Decision Rule.

Under sections 408(e) and 701(a) of FFDCA, EPA will publish a notice in the Federal Register proposing that the use described in the notice qualifies as a Threshold of Regulation use. In a Threshold of Regulation proposal, EPA will identify the pesticide, describe the conditions of intended use, identify the information EPA relied on in proposing its decision, including the analytical method for quantifying pesticide residues in the food, and establish a public comment period.

After the close of the public comment period, EPA will make a Threshold of Regulation decision as appropriate in light of public comments and issue the decision as a final rule. The Threshold of Regulation decision will appear in 40 CFR and will specify the pesticide and intended conditions of use and identify the analytical method considered by EPA for quantifying pesticide residues in the food.

2. Revoke Existing Tolerances for the Use.

EPA will follow existing procedures for revoking any existing tolerances for a use that qualifies as a Threshold of Regulation use.

3. Monitor Compliance (FDA).

This policy does not alter FDA's enforcement in any way. FDA monitors food for pesticide residues. FDA will continue to monitor food in interstate commerce for pesticide

residues. To detect and quantify pesticide residues in a food, FDA may use either the analytical method that EPA relied upon in making the Threshold of Regulation decision or another method. Because the Threshold of Regulation policy is based on the premise that no residues will be found in a food following the use of a pesticide, FDA will continue to regard any residue finding for which there is no tolerance or tolerance exemption as a violation of the FFDCA and would deem the food as adulterated under section 402(a)(2)(B) of the FFDCA.

4. Rescind a Threshold of Regulation Decision.

A Threshold of Regulation determination will remain in effect until new information shows that a specific use of a particular pesticide no longer qualifies for inclusion under this policy. In the event that a new, more sensitive analytical method becomes available and residues resulting from a TOR use are detected with this method, EPA will expedite the evaluation of a tolerance petition for the use. EPA will also consider revoking a TOR decision if, for example: a) new toxicology data indicates that the potential risk exceeded the criterion for eligibility; b) the use results in detected residues; or c) frequent misuse results in detected residues of the pesticide. If EPA finds that a use no longer qualifies as a TOR use and it is not possible to establish a tolerance or tolerance exemption for pesticide residues in or on the food that result from the use, EPA will seek modification or cancellation of the FIFRA registration.

THE AGENCY'S RESPONSES TO PUBLIC COMMENTS ON THE DRAFT FQPA SCIENCE POLICY DOCUMENT:

"Proposed Threshold of Regulation When a Food Use Does Not Require a Tolerance"
(Announced December 4, 1998; 63 FR 67063)
October 18, 1999

The Agency reviewed all comments pertaining to this document that were submitted specifically under this docket (OPP-00569). A listing of the names and affiliations of the individuals submitting comments is provided at the end of this document. The Agency would like to thank these organizations for critically reviewing the document, and for providing recommendations to improve the document. EPA has incorporated many of these recommendations into the revised document. Many of the comments were similar in content, and pertained to general issues concerning the proposed policy or specific sections within the draft document. To facilitate review and consideration of the comments for purposes of revising the document, the Agency grouped and summarized similar comments together.

Unit I of this document is the Agency's response to comments. The numbers used in the discussion below correspond to specific commenters listed in unit II of this document.

Before turning to the public comments, an explanation of terminology will be helpful to an understanding of EPA's responses. EPA has typically used the term "food use" to categorize pesticide uses for the purpose of data requirements and for determining, in general, whether a tolerance is necessary. By "food use" EPA means a use of pesticide in, on, or near food such that there is a possibility of residues in food. Where no such possibility exists or where data have shown that a use otherwise considered a food use does not result in residues, such use would be considered a "non-food use" and the use would generally trigger fewer data requirements and no tolerance would be deemed necessary. Traditionally, however, EPA has not treated all "food-uses" as needing a tolerance. For pesticide uses in connection with crops that serve in whole or in part as animal feeds, EPA has determined that tolerances are not needed for the food products from the animal (e.g., meat and milk) when "it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is no reasonable expectation of finite residues in light of data . . . ." 40 C.F.R. § 180.6(b). The "no reasonable expectation of finite residue" finding is not a determination that there is no expectation of residue but that if there is any residue present, it will be at levels so low as to be unmeasurable. The Threshold of Regulation (TOR) approach outlined in this policy expands slightly the number of pesticide food uses for which a tolerance is not necessary beyond those uses for which there is no reasonable expectation of finite residue. Under TOR, if a pesticide use results in undetectable residue levels using reliable and appropriately sensitive analytical procedure, EPA will take into account both the measurability of any expected residue and the risk posed by such residue in deciding whether a tolerance is needed.

I. EPA's Response to Comments on the December 1998 Proposed Threshold of Regulation Policy

EPA received 22 comments on this notice. The commenters included pesticide manufacturers, grower groups, food processors, industry task forces, trade associations, and State and foreign governments.

A. Is the Proposed TOR Policy Reasonable?

1. Yes, the proposed policy is reasonable.

a. Registrants and agricultural interests generally liked the proposal because it could help certain uses survive reregistration or facilitate registration of new uses of certain pesticides.

Agency Response: EPA believes that the TOR Policy, if properly designed and implemented, can identify pesticide uses for which tolerances are not needed. Pesticide uses that might qualify as TOR uses are uses of pesticides on or near growing crops, livestock, or food. The Agency believes that this policy will help provide a reasonable transition for agriculture as EPA fully implements the Food Quality Protection Act.

b. Two commenters (6, 20) liked the policy because they interpreted it to mean that if a pesticide use results in no detected residues, using an analytical method that has a Limit of Quantitation (LOQ) of 10 ppb or lower, EPA would not need to regulate the residues from the use.

Agency Response: EPA finds that the commenters (6, 20) have misinterpreted EPA's policy statement. Neither approach that EPA proposed for TOR determinations would establish a default level of 10 ppb for regulating pesticide residues in food. A proponent of an "essentially zero risk" determination should establish that there are no residues detected using an analytical method with an LOQ no greater than 10 ppb **AND**, even if residues were present at levels of ½ the LOD, the risk posed by such residues would be of no concern. Under the December 1998 proposal, a proponent of an "essentially zero exposure" determination would need to establish, through special residue chemistry studies, that "there is no reasonable expectation of finite residues in the food." Generally, this means that there would be no detected residues at a level corresponding to 1/10 the LOQ for the analytic method. If the analytical method has an LOQ no greater than 10 ppb, a level corresponding to 1/10 the LOQ would be no greater than 1 ppb. Accordingly, the December 1998 proposal would have used 1 ppb as a threshold for regulating pesticide residues in food, not 10 ppb, as asserted in the comments. However, as explained in unit I.C., the essentially zero exposure approach is not being pursued.

c. The proposal could significantly reduce costs for developing

toxicity data.

A producer of pesticides for seed treatment (14) commented that the adoption of a TOR policy would result in considerable savings in data generation costs. The commenter interpreted the December 1998 proposal to mean that EPA would not require toxicology data ordinarily required to support a potential food use if the pesticide use met the criteria for a TOR determination based upon "essentially zero exposure." The commenter believed that a proponent of such a TOR use would be responsible for providing the more limited toxicity database required to support non-food uses. Producers of pesticides for seed treatment would incur lower costs to develop their products and would be able to get their products on the market sooner if EPA adopts the TOR policy as proposed.

Agency Response: As explained below in unit I.C., EPA has clarified the TOR policy to indicate that toxicity data that are ordinarily required to support the registration of food uses of pesticides are still required to evaluate whether a potential food use qualifies for TOR status. The Agency acknowledges that this approach does not offer the potential savings in product development costs that the commenter inferred from the proposed TOR policy. The Agency recognizes that generating a full toxicity data set to support a TOR determination may be expensive, especially if the pesticide has no uses other than the use being proposed for a TOR decision. The data requirements could discourage development of new products. The Agency is willing to consider, on a case-specific basis, waiving some of its toxicity data requirements.

The Agency also emphasizes that some seed treatment uses may qualify as non-food uses, which require substantially less data than food uses. EPA will consider developing a separate policy specifically addressing seed treatment uses.

2. No, the proposed TOR policy is not reasonable.

a. The TOR policy does not conserve resources

One commenter (7) believes that the proposed policy does not save resources because industry must generate data to support the TOR request and EPA must allocate resources to review these data.

Agency Response: EPA agrees that the TOR policy does not relieve proponents of a pesticide use from their obligation to provide data in support of the proposed use. However, EPA would not perform an aggregate risk assessment, so EPA would use fewer resources to review a proposed TOR use than it would if it were establishing a tolerance or exemption for the use.

b. Risks from a TOR use may not be "of no concern."

One commenter (6) remarked that if the analytical method used to support the registration of a TOR use is very sensitive, but the method used by the Food and Drug Administration (FDA) for compliance monitoring is less sensitive, misuse could occur and not be detected. Actual exposure could be much higher than anticipated in the TOR decision. Risk from such exposure could be higher than "risk of no concern."

Agency Response: While the situation described by the commenter is theoretically possible, EPA believes that it is unlikely to occur, and – even if it does – would not pose a significant hazard to the public. Although misuse is a possibility, legal restraints, i.e., the threat of enforcement action under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), discourage pesticide users from applying more of a pesticide than the product labeling allows. Moreover, economic considerations encourage users to apply less pesticide than allowed by the product labeling. Given the very conservative assumptions used in EPA's calculation of the potential risk of TOR-eligible uses, the Agency believes that the incremental increase in exposure resulting from possibly undetected misuse would contribute very little to the overall exposure and risk. Therefore, the Agency does not believe that the comment provides adequate reason to abandon or significantly modify the TOR policy.

c. TOR policy may discourage development of more sensitive methods.

One commenter (17) observed that the TOR could discourage registrants of TOR uses from developing new, more sensitive analytical methods for pesticides in foods. A more sensitive method might be capable of detecting residues in food resulting from a TOR use. Under the proposed TOR policy, the use would no longer qualify as a TOR use if residues were detected.

Agency Response: EPA believes that adoption of a TOR policy will not have a significant effect on the continued advance of the frontiers of chemistry. There are many individuals and organizations who are interested in improving analytical methods. So, even if a registrant is unwilling to develop a new analytical method because the new method might theoretically jeopardize the status of a product registration, there may be others who are willing to do this work.

d. The TOR Policy would undercut other risk reduction efforts.

One association (17) commented that EPA's statement that analytical methods with levels of detection of 10 ppb are "sufficiently sensitive" has the effect of setting 10 ppb as the target for analytic methodologies. By so doing, EPA is undercutting risk reduction efforts in other areas. For example, EPA's water programs frequently establish Maximum Contaminant Levels (MCL) below 10 ppb and the National Institute of Occupational Safety and Health (NIOSH) recommends

managing contaminants in workplace air at levels below 10 ppb. The commenter asserted that EPA's proposed action would not support efforts to understand human health risks associated with exposure to chemicals at very low concentrations, such as those that may occur in drinking water.

Agency Response: The commenter makes a valid point. EPA has clarified the TOR Policy to specify that analytical methods with levels of quantitation of 10 ppb *in food* are "sufficiently sensitive" for purposes of making TOR determinations for pesticide residues in food. EPA is aware that it is generally possible to measure pesticide concentrations in air or water at much lower levels than is feasible in complex organic matrices such as food. However, because the TOR policy applies to measurement of pesticide residues in food, and not in any other matrix, the criterion for selecting an LOQ for the proposed TOR policy was the level of quantitation that can be achieved in measuring pesticide residues in food.

3. Yes, the policy is reasonable but there are concerns.

a. The proposed TOR policy blurred the distinction between a food use that is subject to FFDCA and a "non-food" use that is not subject to FFDCA.

Agency Response: EPA has revised the TOR guidance to clarify its applicability. EPA did not intend the TOR policy to affect pesticide uses that are classified as "non-food" uses. Rather, EPA intends the TOR policy to apply to "food uses" of pesticides, that is, the types of uses of a pesticide in, on or around growing crops, livestock or food that may -- at least theoretically -- result in measurable residues in food. The TOR Policy applies to pesticide uses that produce no detected residues in food and is intended to establish criteria for judging whether the potential risk from residues that could theoretically occur in food is so low that it is insignificant. If a particular pesticide use meets the criteria, a tolerance will generally not be deemed necessary under section 408 of the FFDCA.

It appears, however, that the proposed "essentially zero" exposure approach for a TOR determination could be interpreted as applying to certain food uses – e.g., uses that result in no finite residues in milk, meat, poultry or eggs. EPA already has procedures for handling "essentially zero" residues in some foods in 40 CFR 180.6(a)(3) and 180.6(c)(3). This regulation specifies that EPA may use special chemistry studies to support a finding that pesticide-treated livestock feed or direct treatment of an animal results in "no reasonable expectation of finite residues" in milk, meat, poultry or eggs and that no tolerances are needed for the human food items. Because a mechanism already exists for managing certain pesticide uses that result in "essentially zero" residues in food, EPA believes that the "essentially zero" exposure approach proposed in the TOR policy is redundant and potentially confusing. To eliminate this confusion, EPA will not use the "essentially zero" exposure approach in its TOR policy.

b. How will users, FDA and other interested parties find out about

decisions made under the TOR policy?

The December 1998 proposal indicated that EPA must be able to document TOR decisions and retrieve this information later. However, the proposal did not indicate what information about a TOR decision would be made public or what form any announcement would take. Some commenters (6, 11) were concerned that pesticide users would be confused if a use on a pesticide product label did not have a corresponding tolerance or tolerance exemption. Trade associations and registrants (11, 14, 18, 20) suggested that EPA issue a kind of "tolerance" to inform the public of TOR decisions and the sensitivity of the method used to demonstrate the absence of residues. Many commenters stated that EPA should maintain a published compendium of TOR decisions. Government agencies informed EPA of their preference that each TOR decision be published as a rule.

Agency Response: The Agency agrees that it should publicly announce TOR decisions and publish a compendium of TOR decisions. The published information will specify the conditions of use and the analytic method used to establish that the use does not result in detectable residues in the food. For reasons discussed below (in unit I.A.3.c) EPA has decided that the TOR decisions will be issued as rules in order to clarify the regulatory status of the use.

c. What is EPA's authority for making TOR decisions?

Several commenters (e.g., L6) stated that EPA should identify the statutory authority it will rely on for establishing TOR decisions. Some commenters (e.g., 18) cited the Agency's procedural regulations for pesticide registration in 40 CFR 152.112(g) to show that FIFRA requires EPA to determine that all "necessary" tolerances or exemptions have been issued before registering a pesticide for a food use. Other commenters (11) believe that section 24(c)(2) of FIFRA also gives EPA authority to determine that a tolerance is not required.

Agency Response: EPA would agree that TOR decisions are an application of 152.112(g) which is a longstanding regulation coordinating EPA's authorities under FIFRA and FFDCA. Authority for issuing TOR decisions as rules is found in section 701(a) of FFDCA and section 408(e). Section 701 states, "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary." The term "Secretary" means "Administrator" with respect to those provisions of FFDCA for which the Administrator of EPA, rather than the Secretary of Health and Human Services, has responsibility. Section 408(e) authorizes EPA to establish by regulation general procedures and requirements to implement this section. EPA interprets this section as authority to issue guidance for making TOR decisions and to establish TOR decisions as rules.

d. How will FDA respond if it finds residues in food that appear to result from a TOR use?

Comments from trade associations and food processors (18, 20) expressed great concern about the status of food that contains detected residues resulting from a TOR use. This circumstance could arise if a TOR use produces higher residues than expected or if the analytical methods used for compliance monitoring are more sensitive than the method considered in the TOR decision. In the December 1998 proposed policy, EPA had indicated that such foods would be considered to be adulterated under section 402 of the FFDCA and would be subject to seizure. Comments from the food industry said that they would not use a pesticide for a TOR use because they cannot risk seizure of the treated food if residues were found in the food. They requested that EPA find a way to establish a "safe harbor" for foods treated with a pesticide in accordance with a TOR decision. Some commenters suggested that EPA rely on FFDCA section 408(l)(5) to legitimize residues that may be found in food as a result of a TOR use.

In its discussions with the Agency, FDA noted the effect that the Community Nutrition Institute v. Young decision (Community Nutrition Institute v. Young, 818 F.2d 943 (D.C. Cir. 1987) has had on that agency's practices. This decision involved an FDA action level, a level that FDA may establish for a contaminant in food to guide it in an enforcement action. Prior to this decision, an "action level" was an enforcement directive that established a level of contamination below which FDA considered enforcement action to be unnecessary. Foods that contained these contaminants at levels above the "action level" were deemed to be adulterated. In Community Nutrition, the court ruled that FDA could not substitute informal "action levels" for rules that set limits on the levels of contaminants in food. In the absence of a rule that established a permissible level for a contaminant, FDA could not use an action level as a binding regulation.

FDA explained that a TOR decision, absent rule-making, is similar to an action level in that: 1) it is an enforcement policy rather than a rule; and 2) it would establish the LOD of the analytical method for a pesticide as the level of pesticide in a food below which EPA considers enforcement of FFDCA section 408 to be unnecessary. As the court ruled in Community Nutrition, a regulatory agency may not use action levels as binding rules without notice and comment rulemaking. If FDA detected any pesticide in a food treated with a pesticide in accordance with a TOR decision, FDA would be obliged to consider the food to be adulterated under section 402(a)(2)(B) of the FFDCA.

Agency Response: EPA has decided that a TOR decision will be based on a finding that FFDCA section 408 does not apply because the available evidence shows that the use will not result in residues in or on the food. If improved analytical methods show that the use does produce residues in or on the food, sections 402(a)(2)(B) and 408 of the FFDCA would apply to such residues.

EPA has considered whether it should establish a rule for each TOR use to exempt pesticide residues from regulation under section 408 of the FFDCA provided that residues

resulting from a TOR use are present at levels at or below the level of detection for the analytical method used to establish whether a particular use food results in detectable residues in the food. Such a rule would have to rely on the de minimis principle as its primary justification. As outlined below, EPA has certain concerns about relying on the de minimis principle as its primary justification for the TOR policy. (See discussion in Unit I.A.3.e.).

Moreover, EPA believes that the commenters may be overly concerned about the possibility that TOR uses will result in residues that are detected by FDA. The TOR use will be supported by data to demonstrate that the use does not result in residues that are detectable with state-of-the-art analytical methods. EPA is confident that it has sufficient expertise, based upon years of experience in evaluating residue chemistry data, to judge the reliability, representativeness and validity of the data supporting a TOR use. Each TOR decision will be published as a rule that specifies the pesticide, the food, the conditions of use, and the analytic method used to establish that the use does not result in detectable residues in the food. Therefore, EPA believes that if FDA finds residues in a food that has been treated with pesticides under a TOR approval, either FDA used an analytical method that is even more sensitive than the method evaluated by EPA or the pesticide user did not carefully adhere to the conditions of the TOR approval (i.e., the pesticide product label). FDA generally provides the public ample notice when it is considering adopting a new analytical method for enforcement purposes. A person who is relying on a TOR approval to support a pesticide use would have opportunity to evaluate the new analytical method before FDA adopts it.

FFDCA section 408(l)(5) ("safe harbor" provision) does not apply in this situation. This provision applies when residues are found after EPA has revoked a tolerance and the residues are below the level of the former tolerance.

e. The criterion that "There must be no residues detected in or on the food" is too restrictive.

(1) The proposed TOR excludes Section 18 uses that result in detected residues.

Some commenters (6, 18) noted that as proposed, the TOR policy would not apply to FIFRA section 18 uses that result in detected residues in or on food. They questioned whether EPA will apply the same criteria to FIFRA section 18 emergency exemptions as it would to FIFRA section 3 registrations, asserting that different criteria could be used for the time-limited and geographically limited FIFRA section 18 uses. An industry task force (18) asserted that EPA had authority to determine that a tolerance or exemption is not required under FFDCA section 408 (l)(6) for a FIFRA section 18 food use. This determination could be based on criteria that consider only the incremental risk posed by the proposed use.

Agency response: There is no basis for including in the TOR policy FIFRA section 18 uses that result in detected residues. A fundamental element of the TOR policy is that a use

results in no detected residues. Therefore, the TOR policy cannot be used to manage the risk posed by FIFRA section 18 uses that result in detected residues.

The Agency will not address in this document whether it may use different criteria for judging FIFRA section 18 uses than it uses to judge FIFRA section 3 or Section 24(c) uses. EPA addressed this issue in the preamble of the recently published FIFRA Section 18 proposed rule (64 FR 29823; June 3, 1999). As part of that rule-making, EPA requested comment on an "incremental risk" option for managing the risk posed by FIFRA Section 18 uses.

(2) A de minimis policy would be more inclusive than the proposed TOR.

Several comments (7, 16, L6, L7) urged EPA to consider a de minimis policy for uses that pose inconsequential risks. According to one commenter (L6), the Agency has underutilized the de minimis principle embodied in Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979). This commenter noted that Monsanto had both defined the legal limit of which substances qualified as "food additives" under the FFDCA, and advised that FDA might use the de minimis principle to decline to regulate some substances that did qualify as food additives. According to this commenter, the de minimis principle would be more simple to implement in practice. This comment also contained considerable discussion regarding how the legal principle of "de minimis non curat lex" can be applied to FFDCA section 408(b). This principle means that an Agency may decide some violations of the law are so trivial that they are not worth regulating. The commenters argued that, if EPA applies this principle, it would be able to find that a residue does not need to be regulated under FFDCA section 408 if a given level of a particular pesticide – based on the hazard characteristics of the pesticide – poses a de minimis risk. Detected residues of a pesticide could also be eligible for consideration under a de minimis policy.

Agency Response: The TOR policy does not rely on the de minimis doctrine as its primary justification. This was a conscious choice by EPA for several reasons. First, despite the fact that the de minimis principle is well-established, there is always some legal risk when an agency asks a court to disregard the plain language of the statute. EPA's approach does not attempt to write an exception to the statutory language as does the de minimis principle; rather, EPA has relied upon the less controversial legal approach of fashioning a reasonable interpretation of existing statutory language -- here, "any pesticide chemical residue in or on a food." EPA's policy describes criteria that will be taken into account in determining when a pesticide can be deemed to be "in or on food" when the pesticide is NOT detectable on the food. EPA's approach of focusing on the risk posed by potential residues is a reasonable interpretation of when zero detected residues means the pesticide is not in or on food. In the event that a court concludes that potential risk is not an appropriate consideration in determining when undetected residues qualify as residues "in or on food," the de minimis principle provides a secondary justification for EPA's approach. Second, reliance on a de minimis theory as a primary justification is only necessary if EPA's policy extends to pesticide residues that are detectable. However, EPA is uncertain whether an expansion of TOR to detected residues posing insignificant risks is necessary to meet

the concerns that have motivated EPA to formulate the TOR policy. If, at some later date, EPA decides to explore an expansion of TOR, EPA would at that time evaluate the application of the de minimis doctrine as the primary justification for the TOR policy. Finally, reliance on the de minimis principle is not needed to meet the practical concerns raised by the commenter. EPA does not believe it will be difficult to apply the criteria in the policy to decide when a pesticide is in or on food. As outlined in the policy, EPA has already been making this type of determination as to a considerable range of pesticide uses.

(3) EPA should adopt a single level of exposure as the threshold of regulation

One comment (L6) urged EPA to abandon its proposed TOR approach in favor of either (1) a single level of exposure, such as 0.5 ppb per day, as the threshold of regulation for any pesticide residue in foods or (2) a level of exposure that is specific for each pesticide, e.g., a fraction of the reference dose (RfD)[5] for the pesticide, as the threshold of regulation for each pesticide. Under this approach, the TOR residue level in a particular food would depend on the relative importance of the food in a person's daily diet. A pesticide residue in a food would be below the threshold of regulation if exposure to the pesticide that is attributable to residues in that food comprised less than either 0.5 ppb in a person's total daily food intake or the pesticide-specific level of daily exposure. Uses that produce measurable pesticide residues would be covered under each of the suggested approaches.

Agency Response. EPA does not agree that a single level of exposure should be used as a threshold of regulation for all pesticides. Many pesticides are inherently toxic; it is likely that a the level of exposure selected by FDA in its TOR policy for certain food additives would not be protective enough for pesticides. EPA reasoned as follows: assuming that the average American adult weighs 70 kg and consumes 1.6 kg of food per day[6], a concentration of 0.5 ppb of pesticide residue in the diet corresponds to a daily dose, expressed in mg/kg/body weight, of 0.000011 mg/kg/day. If a dose of 0.000011 mg/kg/day is to be of no consequence, it should be at least 1000 times lower than the population-adjusted reference dose for the pesticide (see discussion in unit I.D.3). EPA then referred to a compilation of RfDs for 377 pesticides. The RfDs ranged from 4.5 mg/kg/day (least toxic) to 0.00001 mg/kg/day (most toxic). For 197 of these pesticides 0.000011 mg/kg/day is greater than 0.1% of the RfD. This means that for 52% of pesticides, the exposures that would be received by the average adult under the "single level of exposure" approach would pose risks that are greater than inconsequential.

EPA did not perform this analysis for children's risk because children's food consumption

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[5] A reference dose is the amount of a substance that a person can consume every day on a continuous basis without appreciable risk.

[6] Average food consumption as reported in Exposure Factors Sourcebook, American Industrial Health Council, May 1994.

is more variable than that of adults and because population-adjusted RfDs are not available for all 377 pesticides. However, because the ratio of food consumption per unit body weight is generally higher for children than for adults, children would receive a larger dose of pesticide residue in the diet than adults receive when pesticide is present in the diet at a level of 0.5 ppb. Accordingly, for more than 197 pesticides, a daily exposure of 0.5 ppb in children's diets would pose risks that are greater than inconsequential.

The other suggested approach resembles EPA's TOR policy in that it considers the toxicity of each pesticide in establishing a threshold of regulation and expresses the TOR as a percentage of the acceptable exposure for the pesticide. However, as explained above, EPA is not willing to consider a TOR policy that would allow measurable residues to be eligible for a TOR decision.

The commenters further proposed that EPA grant FIFRA registration to any pesticide use that could theoretically result in human dietary exposures that are below the TOR. However, this proposal overlooks key elements of pesticide registration procedure. In evaluating a pesticide use, EPA considers the conditions of the pesticide use and reviews data that characterize the hazards and risks posed by the pesticide. Under FIFRA section 3(c)(5) or 3(c)(7), EPA must determine whether the use of the pesticide meets the FIFRA standard for registration. The commenters' proposal does not appear to contemplate submission of information regarding the conditions of use that would produce residues on the food that are below the TOR. In the absence of specific information about how the pesticide is to be used, EPA would not be able to make the required findings under FIFRA section 3(c)(5) or 3(c)(7).

B. Residue Chemistry Data Requirements for TOR Decisions

1. Some pesticides will not be eligible for TOR because analytical methods are not sensitive enough.

Several commenters (5, 11, 16, 18) objected to EPA's proposed recommendation that the analytical method for the pesticide be capable of quantifying levels of 10 ppb. They suggested that if a pesticide use otherwise met the criteria for "essentially zero" risk, the use should be granted TOR status. One commenter (5) remarked that some pesticides do not contain readily measured atoms such as chlorine, phosphorus or sulphur, so it is not possible to achieve such method sensitivities for all pesticides. The commenter believes that proponents of TOR decisions for pesticides that are difficult to measure are being penalized because their pesticides are not as easily measured as other pesticides.

Agency Response: The 10 ppb level is a recommended level given the current state of science. On a case-by-case basis, EPA will examine whether a higher or lower LOQ is needed.

2. There are alternatives to using ½ LOD as the default residue value in "essentially zero" risk TOR decisions.

Most commenters (5, 11, 18, 19) agreed that it was reasonable to use ½ of the LOD as a surrogate for the potential residue level when estimating dietary exposures to undetected residues that theoretically could occur in pesticide-treated food. One commenter (5) suggested that EPA consider using data from studies of residue disappearance kinetics to predict concentrations that would be expected at harvest. The kinetics of residue disappearance would be established at application rates that result in measurable residues. When the pesticide is applied at lower rates so that no detected residues occur in the treated food, data from the kinetics studies could be used to extrapolate the residue level. This value would be used in the dietary risk assessment for the use. One commenter (7) did not agree with EPA's approach of using ½ LOD as a default residue value when no residues are detected, suggesting that EPA use either "0" or the LOD as the residue value instead. Another commenter (L5) observed that analytical methods are becoming increasingly sensitive and that at some point, methods will be able to detect such low levels of residues that EPA should be able to treat "non-detect" data as "zero residue" data.

Agency response: When estimating dietary exposures from proposed TOR uses, EPA will generally use ½ LOD as a default residue value for samples that show no detected residues. This approach follows Agency policy concerning the use of data showing no detected residues in a food (see 63 FR 67063, December 4, 1998). EPA will substitute other residue values for samples that show no detected residues if data such as the kinetic studies described above were available.

EPA agrees with the observation that methods for quantifying pesticide residues in food are becoming more sensitive and notes that a more sensitive method has, by definition, a lower LOD. However, the fact that no residue is detected – even with a method that is more sensitive than a method previously considered to be state-of-the-art – does not mean that no residues are present. As discussed above, other data may justify using a value (even "0") other than ½ LOD of the most sensitive available method.

EPA will address the objections raised to EPA's approach for handling samples that show no detected residues in its response to the paper "Exposure Assessment – Interpreting 'No Residues Detected'," announced December 4, 1998; 63 FR 67063.

3. Multiple rate studies for seed treatments

A developer of seed treatment products (14) commented on the feasibility of multiple rate studies. In the December 1998 proposal, EPA said that it would use multiple rate studies, performed at 10X the labeled rate, to make a finding that a seed treatment results in "essentially zero" residues in the mature plant. The commenter said that pesticides used in seed treatment are phytotoxic at high concentrations so it is not possible to treat seeds at 10X the labeled rate as EPA has recommended. The commenter wants EPA to accept multiple rate residue chemistry studies performed at 3-5X.

Agency Response: As explained above, EPA is modifying the proposed TOR policy to eliminate the "essentially zero" exposure approach to TOR determinations. Accordingly, EPA will examine toxicology and residue chemistry data to determine if a pesticide use results in "essentially zero"dietary risk to qualify as a TOR use. Nonetheless, multiple rate studies -- including studies performed at 3-5X the labeled rate – would still be useful for demonstrating that the seed treatment use qualifies as a TOR use under the revised criteria.

4. TOR decisions for antimicrobial pesticides

One commenter (11) asked EPA to describe the models and assumptions that EPA will use to determine whether the use of an antimicrobial pesticide qualifies as a TOR use.

Agency Response: The food uses of antimicrobial pesticides include direct use of antimicrobial pesticides in fresh fruit and vegetable rinses and uses in agricultural settings such as the use of disinfectants in irrigation water or algicides in drinking water for livestock. Residue chemistry studies that would be useful in estimating human dietary exposures from such uses are described in the Agency's Residue Chemistry Data Guidelines. For estimating human dietary exposure resulting from other uses, such as use of antimicrobial pesticides on food contact surfaces, EPA may use models developed by the FDA. These include "Recommendations for Chemistry Data for Indirect Food Additive Petitions," and "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions."

5. Residue chemistry data requirements for Section 18 uses or minor uses

The December 1998 TOR policy proposal acknowledged that residue chemistry data needed for a TOR determination may not be available for Section 18 uses or minor crop uses and indicated that surrogate data may be acceptable. Several comments (11, L7) asked EPA to specify surrogate data that could be used to support a TOR decision for a Section 18 or minor crop use.

Agency Response: To make a TOR decision, EPA would need data to show that no residues are detected in the commodity as a result of the use and that the analytical method is suitably sensitive to detect residues if they were present. If there are no data to directly measure pesticide residues in the commodity or to characterize the performance of the analytical method, EPA may accept alternative data that show, or allow the Agency to extrapolate, the necessary information. As is presently done for establishing tolerances to support minor uses, the Agency may accept residue data from a related crop to establish eligibility under the Threshold of Regulation policy. EPA may also adopt the crop group concept from 40 CFR 180.41 when making TOR decisions. In other words, if residues are shown to be not detectable for the representative commodities of a crop group, it will be assumed residues are below the LOD in all other members of that crop group, provided that the conditions of use are comparable.

6. Performance requirements for the analytical method

One commenter (17) suggested that EPA require that analytical methods used to support a TOR decision meet the following criteria: 1) the method should be fully characterized; 2) the method should be demonstrated in several laboratories before it is adopted; 3) the method performance should be appraised through peer reviewed literature or consensus method of the American Standards and Testing Methods (ASTM). The method should be usable by federal compliance monitoring laboratories.

Agency Response: The Agency agrees the methods should be thoroughly tested prior to acceptance and believes the present procedures ensure that. Analytical methods are required to be validated by the petitioner, an independent laboratory unfamiliar with the procedure, and by the Agency's own analytical laboratory. That same process will be followed for methods associated with TOR decisions.

C. Toxicity Data Requirements for TOR Decisions

A government agency (19) recommended that EPA require toxicity information for all food uses that are potential TOR uses, including seed-treatment uses. Under the "essentially zero" exposure approach described in the December 1998 proposal, a proponent of a TOR use would not be required to present any data for characterizing the hazard posed by dietary exposure to the pesticide.

Agency Response: When EPA originally proposed "essentially zero" exposure criteria for TOR decisions, it reasoned that if exposure is "essentially zero," risk would also be "essentially zero." EPA has reconsidered this position, however, because it cannot conclude with certainty that very low exposures, even "essentially zero" exposures, are without risk if there significant gaps in the information about the biological activity of the pesticide. The "essentially zero exposure" approach proposed in the December 1998 TOR Policy would have established a level in the range of 1 ppb as "essentially zero." If EPA were to adopt the "essentially zero exposure" approach for TOR decisions, the Agency would be concluding that risk from exposure to 1 ppb of any pesticide, regardless of toxicity and the crop which it would be used, would always pose risks of no consequence, or "essentially zero" risk.

Some pesticides, however, are so toxic that exposures of 1 ppb may pose risks greater than "inconsequential" or "essentially zero" risk. The Agency will perform a quantitative risk assessment before concluding that a specific use poses "essentially zero" risk from dietary exposures. Accordingly, EPA expects to evaluate the array of toxicity data that are normally used in a dietary risk assessment in order to identify health hazards and quantify a dose response. (See 40 CFR 158.340.) On a case-by-case basis, however, the Agency may waive specific toxicity data requirements, based upon a pesticide's known toxicity, structure-activity relationships, and estimated exposures.

D. Risk Criteria for TOR Decisions

1. EPA's TOR risk criteria are overly stringent.

Several commenters (5, 8, 11, 13, 16, L6) asserted that few pesticide uses would meet the TOR criteria for the "essentially zero" risk approach and recommended that EPA ease the criteria for "essentially zero" risk so that more uses could qualify for TOR decisions. One commenter (5) observed that the EPA's proposed TOR policy, whereby dietary exposure to a pesticide at 0.1% of the acceptable level of risk is considered to be of no consequence, is "risk management policy," not "science policy."

Another commenter (13) provided an analysis to show that the proposed TOR risk criteria are much more protective than EPA realizes. Under the "essentially zero" risk approach for TOR, the level of detection (LOD) for a pesticide represents 1/500 of the acceptable risk (i.e., exposure to residues at a level of ½ LOD results in risk that is 1/1000 of acceptable risk). If the mean level of residues is ½ LOD and the Standard Error for the measurements is 0.7, the probability of detected residues would be 16%. Therefore, if there are no detected residues in a food treated with pesticides under a TOR use, the mean level of residues must be considerably below ½ LOD. According to this analysis, the probability of exposures resulting from a TOR use reaching a level of 1/10 of acceptable risk would be 2.4×10^{-11}. If the LOD for a pesticide represents 1/50 of the acceptable risk (i.e., exposure to residues at a level of ½ LOD results in risk that is 1/100 of acceptable risk), the probability of residues reaching a level of 1/10 of acceptable risk would be 5×10^{-4}. The commenter believes that the risk resulting from exposures of 1% of the acceptable risk level would be of no consequence.

One commenter (L6) speculated that EPA did not choose 1% of acceptable risk as the risk criterion for TOR decisions because EPA imagined that 100 TOR uses would fill the "risk cup," leaving no "room"in the risk cup for other uses. The commenter dismissed this reasoning as overly simplistic. The commenter supposed that another possible reason for EPA's rejection of 1% as the TOR risk threshold could be that EPA may believe a person could receive exposures from a multitude of TOR uses and that EPA may believe that the aggregate risk from these exposures could be significant. The commenter believed that it is not reasonable to suppose that a person could receive exposures from 100 sources each of which contains the maximum residues allowed under a TOR policy.

One commenter (16) stated that a TOR risk criterion of 1% of the RfD would be consistent with the risk criteria FDA uses in its threshold of regulation policy for indirect food additives and asked EPA to explain why 1% of the RfD was not selected. A comment from a state agency (L7) opined that there was no scientific basis for requiring a showing of "essentially zero" risk and asserted that sufficient protection would be achieved if the risk posed by the TOR use is "an insignificant proportion of allowable risk."

Agency Response: The Agency agrees with the commenter that the selection of risk criteria for the TOR policy is a risk management rather than a science policy decision. EPA intends that the exposures from TOR uses be so small that risk resulting from such exposures

would be of no concern.

EPA would note that the commenter's assertions about the extreme improbability of receiving exposures above the LOD when TOR decisions are based on the proposed risk criterion of 1/1000 of acceptable risk related to exposure at a single meal. That, however, is not the only exposure scenario with which EPA is concerned.

Because selection of the risk criteria for TOR decisions is a risk management decision; the risk level itself should connote the triviality of the risk. With the caveat noted above, the commenter's analysis of the probability of exposure exceeding the acceptable risk from a single meal is supportive of the trivial nature of the risk of pesticide uses meeting the TOR policy. However, EPA does not rely on a statistical analysis of the probability of detected residues alone to justify its decision that exposures at a particular level pose inconsequential risks. The Agency must communicate TOR decisions to many audiences. Some people may have a very concrete understanding of the "risk cup" concept. To their minds, a use that occupies 1% of the risk cup does not pose an inconsequential risk, just as a penny does not pose an inconsequential part of a dollar. A person with a literal understanding of the risk cup concept may, however, accept the notion that 0.1% of acceptable risk is really of no consequence and can be dismissed. The Agency believes that a risk of 0.1% of the acceptable level of risk is of no consequence.

2. Few uses will meet the proposed criteria.

Many commenters expressed the opinion that EPA's criteria for "essentially zero" risk TOR decision are so strict that few uses would qualify.

Agency Response: Under the revised TOR policy, proponents of a TOR use should establish that the use meets two criteria to establish that the use poses "essentially zero" risk: 1) the use results in no detected residues, using a valid sufficiently sensitive analytical method; and 2) the risk posed by residues at levels of ½ LOD should generally be no greater than 0.1% of acceptable risk. EPA does not have the data to assess how many pesticides would qualify for the first criterion, but the Agency does have information to show that the second criterion is not overly restrictive.

EPA conducted its own analysis to see how many pesticide uses could qualify for TOR exemptions, using the following parameters and assumptions: The proposed TOR policy indicated that no residues be detected using a method capable of quantifying 10 ppb and that EPA would assume that residues to be present at ½ the LOD. For this analysis, residues were assumed to be present at ½ the LOQ, i.e., 5 ppb, instead of ½ LOD (½ LOQ is slightly higher than ½ LOD). EPA selected various dietary items that comprise either "large," "medium," or "small" components of the diet and calculated the dietary exposures to residues in or on each of the selected commodities for either the general U.S. population or children aged 1 through 6 years. EPA then referred to a compilation of reference doses (RfD) for 377 pesticides. The RfDs ranged from 4.5 mg/kg/day (least toxic) to 0.00001 mg/kg/day (most toxic). EPA assessed the number

of pesticides for which the exposure due to consuming wheat, apples, pears or asparagus that contain 5 ppb of pesticide was less than either 1%, 0.5% or 0.1% of the RfD for the pesticide. The results are shown in Table 1. The results suggest that virtually any pesticide will qualify for a TOR for use on a food item that is a "small" component of the diets of the general U.S. population or children aged 1 to 6 years, provided the residues are undetected and the LOQ of the analytical method is below 10 ppb.

The analyses presented in Table 1 examined the applicability of the revised TOR to pesticides that exhibit toxic effects for which a threshold dose, or "no observed adverse effect" dose can be established. A preliminary assessment of carcinogenic pesticides suggests that it may be possible to make TOR decisions for uses of carcinogenic pesticides on items that constitute minor components of adult diets. EPA believes that many pesticide uses could qualify for TOR approvals even when the Agency defines inconsequential risk to be 0.1% of the acceptable level of risk. Therefore, it is not necessary to modify the risk criteria, as suggested in the comments.

3. What criteria would be used to define "essentially zero" risk for infants and children?

One commenter (18) asked what "acceptable risk" meant with respect to risks to infants and children or other subpopulations when EPA stated that risks from a TOR use would be less than 0.1% of acceptable risks.

Agency Response: The December 1998 proposed policy did not explain how EPA would handle risks to infants and children from a TOR use. EPA agrees with the commenter that the Agency's position must be clarified.

In evaluating the incremental dietary risk posed by a pesticide, EPA will consider the nature of the hazard posed by the pesticide. For pesticides that exhibit toxic effects for which a threshold dose, or "no observed adverse effect" dose, can be established, EPA will evaluate the dietary risks that would result from a single exposure and from continuous exposures to the food that has been treated with a pesticide under a TOR decision. At issue is whether EPA will separately evaluate the incremental dietary risk posed by a proposed TOR use to each population subgroup, particularly infants and children, and consider other FQPA issues such as the additional safety factor for infants and children.

Because this is a policy to guide EPA's decision-making about what assumed residue levels pose so insignificant a risk as to not need tolerances under section 408, EPA believes it should be guided by section 408 in assessing the level of risk. To make a credible assertion that a TOR use poses inconsequential risks, the Agency's assessment will include a separate assessment of the risk from food to subpopulations, including infants and children as specified in section 408. In addition, if EPA has not established an FQPA safety factor, EPA will, as a matter of policy, decide the appropriate FQPA safety factor and will use it when evaluating the potential risk posed by the proposed TOR use to infants and children.

Table 1. Pesticide uses that would qualify for TOR decisions at various risk criteria levels.

PESTICIDE USES THAT WOULD QUALIFY FOR TOR DECISIONS AT VARIOUS RISK CRITERIA LEVELS				
Chronic Exposures Assume residue in food of 5 ppb RfD values for chronic toxicity effects for 377 active ingredients Risk Criteria: 1%, 0.5%, or 0.1% of Chronic RfD				
CROP	EXPOSURE (mg/kg/day)	NUMBER of CHEMICALS where EXPOSURE is less than		
		1% RfD	0.5% RfD	0.1% RfD
Population Subgroup: U.S. population				
Wheat	0.000007	315	295	222
Apples	0.000005	329	313	253
Pears	0.000001	356	350	313
Asparagus	0.00000006	377	374	359
Population Subgroup: Children aged 1-6 years RfD for chronic toxicity effects not adjusted for FQPA safety factor				
Wheat	0.000017	292	266	159
Apples	0.000020	282	258	134
Pears	0.000001	352	343	301
Asparagus	0.000000008	377	377	377

4. There should be special TOR criteria for seed treatment uses.

A developer of seed treatment products (14) wanted the opportunity to demonstrate that seed treatment uses result in “essentially zero” exposures. The commenter proposed alternative data requirements and criteria for demonstrating that seed treatments result in “essentially zero” exposures. A grower group (12) that produces seed crops from treated seed asked that the Agency’s TOR process be modified to include “screenings” and straw derived from the seed crops. Seed crop producers may not feed to livestock the screenings and straw from their seed crops because there is a concern that there will be pesticide residues in the mature plant, including such tissues as screenings and straw. Seed crop producers must maintain records to show that screening and straw from the seed crop were not fed to animals. The TOR policy could eliminate

this paperwork requirement.

Agency Response: The Agency will apply the criteria in the revised TOR Policy to seed treatment uses. As discussed above in unit I.C., a proponent of a TOR use would normally need to submit the full toxicity data set for a food use. EPA will, however, consider waiving toxicity data requirements on a case-by-case basis.

With respect to screenings and straw, the TOR policy covers all potential food or feed forms produced from a crop. Thus, EPA would set a tolerance or tolerance exemption for residues in screenings or straw from a seed crop unless data showed that the TOR criteria were met for these food forms.

The comments argue that seed treatments are different from the potential food uses covered in the TOR Policy and that different criteria should be applied. EPA will reserve these issues for future discussion.

E. How Will EPA Handle Risks from Other Exposures That Result from a TOR Use?

1. How would EPA account for drinking water exposures that may result from a TOR use?

One comment (17) indicated that EPA should clarify how it will handle drinking water exposures that may result from a TOR use. A TOR use could result in residues getting into drinking water supplies. Would EPA assess the incremental risk from drinking water when evaluating a proposed TOR use? Would EPA grant TOR status if the use is expected to result in exposures to the pesticide from drinking water? Would EPA apply the same risk criterion – 0.1% of acceptable risk – to risk from potential residues in drinking water?

Agency Response: After EPA has determined that a proposed new use meets the criteria for a TOR use and that no tolerance is required, the Agency will review the use to determine whether it meets the standard for registration in section 3(c)(5) or 3(c)(7) of FIFRA. Among other things, section 3(c)(5) specifies that the pesticide will perform its intended function without unreasonable adverse effects on the environment. Section 3(c)(7) similarly specifies that the pesticide will not increase the risk of unreasonable adverse effects on the environment. FIFRA defines “unreasonable adverse effects” at section 2(bb).

In 1996, the FQPA amended section 2(bb) of FIFRA to coordinate FIFRA with section 408 of the FFDCA. An unreasonable adverse effect is now defined as: (1) any unreasonable risk to man or the environment . . . ., or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug and Cosmetic Act . . . .” FIFRA section 2(bb)(2) applies to a registration decision when a tolerance is required for the use under consideration or the use otherwise results in residues in or on food. Accordingly, when deciding whether to register a use that meets the criteria for TOR status, EPA will apply FIFRA section 2(bb)(1) to decide whether pesticide

residues in drinking water that are attributable to the proposed use pose an unreasonable risk.

2. How would potential exposures from a TOR use be handled in an aggregate risk assessment?

One commenter (11) asked how EPA would address potential exposures from a TOR use in an aggregate risk assessment of the pesticide. The commenter was concerned that a TOR use would be eliminated if a subsequent aggregate risk assessment showed that risks from a TOR use are unacceptable.

Agency Response: Generally, EPA would not consider potential food exposures from a TOR use in an aggregate risk assessment of the pesticide. The risk ceiling for a TOR use should be low enough that exposure (e.g., drinking water or other non-occupational exposure) from the TOR use would not have a measurable effect on aggregate exposure and risk. If aggregate risk for a pesticide is found to be unacceptable, EPA would consider the TOR use in determining what uses would have to be canceled, but EPA would be unlikely to focus its cancellation efforts on uses (such as TOR uses) that pose no significant risk.

F. Procedural Issues

1. Will EPA evaluate all existing and prospective uses for TOR eligibility?

Several commenters (8, 11, 14, 18, 19) addressed operational issues, asking whether EPA would evaluate: 1) all prospective uses for TOR eligibility or only those where the registrant requests TOR status; and 2) all existing uses for TOR eligibility.

Agency response: EPA believes that the TOR policy should be applied consistently and uniformly. Accordingly, the Agency intends to evaluate all existing and prospective uses for TOR eligibility. The Agency will evaluate the TOR eligibility of existing food uses during tolerance reassessment, reregistration or registration review. The Agency will also evaluate the TOR eligibility of all prospective uses during the risk assessment process and determine whether a tolerance is needed.

2. Will EPA charge tolerance fees for TOR eligibility evaluations?

Commenters on this issue (11, 18) asserted that a person should be able to request a TOR exception without petitioning for a tolerance and paying a fee. According to FFDCA section 408(m)(1), a fee can only be charged for actions under FFDCA section 408. Since a TOR review does not lead to an action under 408, a fee cannot be charged.

Agency Response: TOR eligibility determinations involve application of FFDCA section 408. The decision whether FFDCA section 408 applies to a particular case is itself a section 408 action. Accordingly, EPA could require payment of a "tolerance fee" to cover the costs of

evaluating a TOR eligibility request. However, the Agency does not intend to do so at this time.

3. How will EPA handle tolerances for existing uses that are found to be eligible for TOR status?

Commenters offered two points of view on how to handle tolerances for existing uses that are found to be eligible for TOR status. One commenter (16) suggested that EPA should request public comment on three options: a) tolerance exemption; b) reduce the tolerance to the LOQ of the new method; or c) keep the tolerance as is. Other commenters (8, 11,14, 18, 19) stated that once a TOR is established for a use, the tolerance is no longer needed and should be revoked. These commenters emphasized the public's need for consistent application of Agency policy to existing uses and new uses; if an existing tolerance is not needed, it should be revoked. Such revocations should not be given special priority.

Agency Response: The Agency believes that it should revoke tolerances after it has decided that a specific pesticide use qualifies as a TOR use. EPA finds that it would not be in the public's interest to adopt the suggestion that tolerances for uses that are eligible for TOR status be either retained or modified. It would be confusing if there were TOR decision rules for some uses and tolerances for other uses that are eligible for TOR status. Converting a tolerance to a tolerance exemption may be inappropriate because exemptions from tolerance do not establish limits on the residue levels, and the residue levels of a pesticide may need to be limited for safety reasons.

4. Who can apply for a TOR?

One commenter (12) asked that states or growers be able to request TOR decisions for pesticide uses.

Agency Response: EPA agrees with this comment and will clarify the TOR Policy to make it clear that anyone may ask EPA for a TOR decision.

5. Rescission of a TOR decision

Several commenters (8, 16) recommended that a TOR decision not be revoked if residue detections are due to occasional misuse. Rescission is appropriate if investigation shows that the TOR decision should not have been issued. Another commenter said that a TOR decision should not be revoked because of availability of a new method that can detect residues resulting from a TOR use.

Agency Response: The Agency agrees that enforcement would generally be a more appropriate regulatory response than revoking a TOR decision when residue detections are due to isolated incidents of misuse. The Agency agrees that rescission is appropriate when new information shows that the TOR should not have been issued. New information, however, may

include availability of a new analytical method that can detect residues resulting from a TOR use. In this circumstance, EPA would consider a petition for a tolerance for residues resulting from the TOR use.

G. Should TOR Policy Be Issued as Guidance or as a Rule?

Several commenters (11, 16, 18, 19) urged EPA to issue the TOR policy as a rule. Some commenters recommended that EPA delay issuing the policy as a rule until the Agency has had some experience with the policy. Reasons given for issuing the policy as a rule include: 1) TOR will be applied to section 18 exemptions and the FFDCA requires EPA to issue regulations regarding establishment of tolerances and exemptions for section 18s; 2) a rule clarifies status of the policy and eliminates some procedural grounds for challenging it; 3) criteria for TOR status would appear in CFR with other regulations; and 4) the approach provides an opportunity for stakeholders to comment on the policy. One commenter (8) preferred that EPA issue the policy as guidance rather than as a rule.

Agency Response: EPA has decided to issue the TOR policy as guidance and to defer issuing the policy as a rule until it has gained a body of experience in using this policy. Furthermore, EPA prefers to begin applying the policy now, rather than waiting until a procedural regulation becomes final. As discussed above in unit I.A.3.b. and c., EPA will issue individual TOR decisions as rules. EPA believes that these regulations will accomplish most of the objectives identified above. EPA acknowledges that it would be more convenient for the public if the criteria for making TOR decisions were located in the CFR with other regulations, but finds that its need for flexibility overrides its desire to codify its TOR decision criteria. To assure that the public has continued access to the latest version of the TOR policy, EPA will maintain a copy of each version of the TOR policy in the public docket for the TOR policy and post the current iteration of the TOR policy on its Internet website.

H. Effects of the Policy on Trade

1. Notification requirement

One comment (6) addressed the U.S. EPA's obligation under FQPA to discuss the impact of its tolerance actions on international trade. The commenter claimed that because a TOR decision is a decision to approve a use without setting a tolerance, it may be the kind of decision for which discussion specified in FFDCA section 408 (b)(4) is required. This provision stipulates that, if EPA's tolerance is established at a level different from a Maximum Residue Level established by the Codex Alimentarius Commission, EPA shall publish for public comment a notice explaining the reasons for departing from the Codex level.

The Canadian government commented that it could support the U.S. EPA's TOR policy provided that the EPA clearly explains its rationale, including the data supporting individual determinations, for not establishing a tolerance.

Agency Response: Because a TOR decision means a tolerance is not necessary under FFDCA section 408 for the residues that may result from the use, EPA believes that the FFDCA section 408 requirements, such as 408(b)(4), do not apply. Nonetheless, EPA plans to publish a rule for each TOR use under FFDCA sections 408(e) and 701. EPA expects that these rules would provide the analysis specified in FFDCA section 408(b)(4). The Agency believes that the notice and comment rule-making for TOR uses would satisfy the concerns of the Canadian government.

2. Potential trade irritant

Several commenters (6, 11, 16) alleged that the TOR policy could produce trade irritants. For example, if a foreign grower uses a pesticide with a TOR clearance, detected residues might occur in the commodity because of some circumstance that was not considered in the U.S. EPA's review of the pesticide. The commodity would be denied entry into the U.S. In another example, if a U.S. grower uses a pesticide with a TOR clearance, commodities with undetected residues may be sent to a country where use of the pesticide has not been approved. This could be a trade irritant because it could give U.S. producers an advantage over local producers of the same commodity. One commenter (11) suggested that the proposed TOR policy would not promote harmonization with trading partners because countries who rely on EPA actions when setting their own standards may misunderstand TOR policy. One commenter (6) suggested it would be appropriate for North American Free Trade Agreement (NAFTA) members to develop a position on this issue jointly.

Agency Response: In the first example, foreign food producers or others could apply for a tolerance for the residues on imported commodities. In the second example, the receiving government would have the opportunity to express its concerns in comments to a published notice about EPA's intent to find that a particular pesticide use qualifies for TOR status. EPA will communicate the TOR policy carefully in order to minimize misunderstandings. By publishing individual TOR decisions, EPA would delineate what is covered, and what is not covered, under the U.S. policy.

With respect to the suggestion that the EPA bring the TOR issue to NAFTA, the Agency believes that such consultation is not necessary at this time. EPA's TOR policy does not appear to raise any issues that negatively affect trade among NAFTA partners. Should issues arise, EPA would consider how best to address them.

3. TOR could enhance trade

A State regulatory agency (8) stated that adoption of the TOR policy would enhance trade, especially for treated seed. The State reported that it has registered some seed treatments under section 24(c) of FIFRA for use only on seeds intended for export because there is no U.S. tolerance for the residue on seeds. If EPA finds that such uses are eligible for a TOR determination, the seed-treatment use could be registered under FIFRA section 3 for use

throughout the U.S. or under FIFRA section 24(c) for use within the State granting the FIFRA 24(c) registration.

Agency Response: EPA agrees that application of the TOR policy would clarify the need for a tolerance for food grown from treated seeds and may lessen potential barriers to interstate commerce of treated seed. However, the TOR Policy does not seem to have much impact on international trade.

II. List of Commenters

Number	Name and Affiliation
1-3	EPA-generated documents.
4	(time extension request)
5	Arthur Craigmill et al., *Extension Toxicology Network.*
6	Chris Warfield, *AgrEvo*, Gloucester, Ontario, Canada.
7	Daniel Byrd, *Consultants in Toxicology, Risk Assessment and Product Safety,* Washington, DC.
8	George Robinson, *Idaho State Department of Agriculture*, Boise, ID.
9	(misfiled item from another docket.)
10	Elaine Vargas, *Novigen Sciences*.
11	Priscilla Friedman, *DuPont Agricultural Products,* Wilmington, DE.
12	Blair Wilson, et al., *Food Producers of Idaho, Inc.,* Meridian, ID.
13	Michael Ginevan, *M.E. Ginevan and Associates,* Silver Spring, MD.
14	*Gustafson LLC*.
15	Christian Herr, *Pennsylvania Department of Agriculture,* Harrisburg, PA
16	Dave Whitacre, *Novartis*.
17	John Sullivan, *American Water Works Association,* Washington, DC.
18	Mark Maslyn, *FQPA Implementation Working Group,* Washington, DC.
19	C. A. Franklin, *Health Canada, Pest Management Regulatory Agency,* Ottawa, Ontario, Canada.
20	Stacey Zawel, *Grocery Manufacturers of America,* Washington, DC.
21	(Duplicate of item 4.)

L1	John Rossner, *Oregon Farm Bureau,* Salem, OR.
L2	John Lincoln, *New York Farm Bureau,* Glenmont, NY.
L3	Jack Laurie, *Michigan Farm Bureau,* Lansing, MI.
L4	Sam Moore, *Kentucky Farm Bureau,* Louisville, KY.
L5	Sharon Hayes, *Dole Food Company, Inc.*, Westlake Village, CA.
L6	Andrew Jovanovich, *Keller and Heckman, LLP*, Washington, DC.
L7	Jean-Mari Peltier, *California EPA/Department of Pesticide Regulation,* Sacramento, CA.